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21967 7590 07/26/2010 HUNTON & WILLIAMS LLP INTELLECTUAL PROPERTY DEPARTMENT 1900 K STREET, N.W. SUITE 1200 WASHINGTON, DC 20006-1109				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Claims 1, 9-11, 17, 24, 28-32, 34-37, and 39-43 are pending in the application. Applicant's request for reconsideration in the amendment after final rejection, filed on 6/30/10, is acknowledged.

Rejections and/or objections previously applied to claims 12, 33, 38, and 44 are withdrawn solely in view of the instant amendment to cancel these claims.

The objection to claims 9-11, 17, 28-29, and 32 is withdrawn in view of the instant amendment to claims 9-11, 17, 28-29, and 32 to replace "A method" with "The method".

The rejection of claims 1, 9-10, 17, 24, 30-31, 37, and 43 under 35 U.S.C. 103(a) as being unpatentable over Dickely as evidenced by Luksas is maintained for the reasons of record and the reasons set forth below. The rejection was fully explained in a prior Office action. See [14] beginning at p. 6 of the Office action mailed on 3/30/10.

At p. 9 of the instant remarks, applicant argues the rejection is based on an unreasonable interpretation of the phrase, "keeping the milk under conditions where the bacterial culture is able to acidify the milk" in claim 1 and similar phrases in claims 30 and 31. Whereas the examiner has interpreted the phrase to refer only to keeping milk at appropriate culture conditions suitable for milk acidification without requiring active acidification of the milk, applicant takes the position that this limitation requires acidification of milk.

Applicant's argument is not found persuasive. The examiner maintains that a broad and reasonable interpretation of the noted phrase does not require any temporal limitation to achieve acidification of the milk. The limitation requires only "keeping" milk at appropriate culture conditions that suitable for milk acidification. If applicant intends for the claim to actively require acidification of the milk, applicant is encouraged to amend the claims accordingly, particularly as "[a]pplicant always has the opportunity to amend the claims during prosecution, and broad interpretation by the examiner reduces the possibility that the claim, once issued, will be interpreted more broadly than is justified" (MPEP 2111).

Beginning at p. 9 of the instant remarks, applicant argues the interpretations of "acidify" and "ferment" as meaning "any aerobic or anaerobic breakdown of organic compounds by a bacterial culture with the production of an end product" in accordance with the specification's description of "fermentation" at p. 6, lines 4-5 is unreasonable. According to applicant, this interpretation "defies common sense and is inconsistent with the way those terms are used in the art" and the phrases should be interpreted according to the specification's description of "fermentation failure" and that acidification is determined in the specification as requiring a measurable pH change.

Applicant's argument is not found persuasive. According to MPEP 2111, the claims should be given their broadest reasonable interpretation *in light of the specification*. Because MPEP 2111.01.IV acknowledges that an applicant may be his or her own lexicographer, the examiner has reviewed the specification to construe intended meanings of the terms "acidify" and "ferment". The specification clearly sets

forth a description of what is intended as being encompassed by the term "fermentation", which is viewed as being the closest representative term to "acidify" and "ferment". Even though this is the closest representative term to "ferment", applicant interestingly asserts this is not the intended meaning that should be applied to the term "ferment". Moreover, applicant asserts "acidify" should be interpreted to require a measurable pH change, even though the claims do not require such a limitation. In accordance with MPEP 2111, the examiner has applied the specification's description of "fermentation" to the terms "acidify" and "ferment". The examiner's interpretation of the terms "acidify" and "ferment" are entirely in line with this description and the claims have been interpreted accordingly.

Beginning at 10, applicant argues the examiner's interpretation of "acidify" and "ferment" as being based on the specification's description of "fermentation" at p. 6, lines 4-5) "lacks any legitimate basis" because the specification states "relates to" and not "is defined as".

Applicant's argument is not found persuasive. Regardless of whether or not the description of "fermentation" is expressly set forth by the term "is defined as" or "relates to", the specification nonetheless sets forth a description of the term "fermentation" and one of skill in the art would recognize the disclosure of "any aerobic or anaerobic breakdown of organic compounds by a bacterial culture with the production of an end product" as a clear intent to describe what is intended as being encompassed by the term "fermentation", which, as noted above, is viewed as being the closest representative term to "acidify" and "ferment".

Returning to the rejection's interpretation of the claims as not requiring active acidification or fermentation, at p. 11 of the instant remarks, applicant argues the examiner's interpretation the claims is inconsistent with the preambles of the claims'. Applicant's argument is not found persuasive. As noted in the prior Office action, while it is acknowledged the preambles of claims 1 and 30 recite "method of fermenting milk" and "method for keeping the capability of a bacterial strain to ferment milk", respectively, the phrases "of fermenting milk" and "to ferment milk" are interpreted as intended use limitations of the claimed method and have not been interpreted as requiring active fermentation of milk.

Beginning at p. 11 of the instant remarks, applicant argues the examiner's asserted motivation for culturing the DN209/pFDi19 strain of *Dickely* in milk, *i.e.*, to select and confirm that the strain is pur-, is not a valid motivation because this selection rationale does not elaborate on how milk could be used for selecting purine auxotrophs. Applicant further argues that the rejection does not explain why one would have chosen milk as a selection medium for testing auxotrophy rather than a conventional medium lacking purines.

Applicant's argument is not found persuasive. Initially, it is noted that the remarks reference certain teachings of *Dickely* at pp. 842 and 845 (remarks at p. 11, bottom). However, the reference of *Dickely*, *i.e.*, US Patent 5,691,185, appears to be only 40 pages. As to the argument that the selection rationale does not elaborate on how milk could be used for selecting purine auxotrophs, this would appear to be self-evident in the teachings of *Dickely* that milk is a medium which does not contain precursors for the

synthesis purine nucleosides in host cells, thus making milk a selective medium for screening for purine auxotrophic mutants (e.g., column 11, lines 50-54 and column 30, lines 54-64). Moreover, Dickely provides exemplary methodology for using milk as a selection medium at column 27, lines 48-58. These teachings alone are sufficient to enable a skilled artisan to use milk as a purine auxotroph selection medium and require no further disclosure with regard to eliminating residual purines to arrive at a "usable growth medium" as asserted by applicant. Regarding applicant's argument that the rejection does not explain why one would have chosen milk as a selection medium for testing auxotrophy rather than a conventional medium lacking purines, Dickely expressly teaches milk as a selection medium for purine auxotrophs, which would appear to be sufficient for one to choose milk as a selection medium for purine auxotrophs.

At p. 12 of the instant remarks, applicant argues the claimed methods require conditions sufficient for fermentation or acidification of milk, however, there is no stated justification to use a sufficient inoculum or culture duration to achieve fermentation or acidification of milk. According to applicant, one would have used a "very low" inoculum to minimize background growth, citing "general scientific principles" that are asserted to be supported by p. 842 of Dickely.

Applicant's argument is not found persuasive. As noted above, there is no claim limitation that actively requires fermentation or acidification of milk, including limitations that require a particular inoculum or culture duration. As further noted above, even if the claims require active fermentation or acidification of milk, the examiner maintains that by

culturing the purine auxotroph in milk according to Dickely, fermentation or acidification (according to the specification's description of milk) would have occurred. While applicant asserts one would have preferred to have used a "very low" inoculum based on "general scientific principles", there is no evidence of record to support this allegation and thus appears to be speculation. The examiner acknowledges applicant's reliance on p. 842 of Dickely, however, as noted above, the reference of Dickely does not have a page 842.

At least for the reasons of record and the reasons set forth above, the examiner maintains that the methods of claims 1, 9-10, 17, 24, 30-31, 37, and 43 would have been *prima facie* obvious at the time of the invention.

The rejection of claim(s) 11, 34, 36, 39, and 41-42 under 35 U.S.C. 103(a) as being unpatentable over Dickely as evidenced by as evidenced by Luksas as applied to claims 1, 9-10, 17, 24, 30-31, 37, and 43 above, and further in view of Barach as evidenced by Groboillot is maintained for the reasons of record and the reasons set forth below. The rejection was fully explained in a prior Office action. See [15] beginning at p. 12 of the Office action mailed on 3/30/10.

Beginning at p. 13 of the instant remarks, applicant addresses claims 11, 34, 39, and 42, arguing one would not have combined the references of Dickely and Barach because Dickely teaches the DN209/pFDi19 strain is non-replicating in milk, while Barach is concerned with fermentation resulting from inoculation of a replicating strain. According to applicant, there is no evidence to suggest that one would have used a

"relatively high inoculum" as taught by Barach for testing growth ability. Applicant again relies on alleged "general scientific principles" asserted to be supported by Dickely.

Applicant's argument is not found persuasive. It is undisputed that Barach teaches that when culturing a microbe in milk, it is desirable to use 10^8 CFU/mL (Barach at column 1, lines 14-19). What is in dispute is whether or not one would have used the inoculum taught by Barach in culturing according to Dickely. Here, applicant provides no objective evidence of record to suggest that one would not have used the inoculum of Barach in culturing according to Dickely. Applicant asserts that in view of "general scientific principles", one would not have used the inoculum of Barach. However, there is no objective evidence of record to support this allegation and thus appears to be speculation. The examiner acknowledges applicant's reliance on teachings of Dickely that allegedly support this position, however, such teachings do not appear to be present in the reference of Dickely as relied upon in the rejection.

Barach makes no distinction as to whether or not the strain is proliferating or non-proliferating and one would have applied the inoculum taught by Barach in culturing according to Dickely. This is at least because the growth analysis or plasmid analysis of Dickely uses a control strain that is cultured in the presence (proliferating) of added purine (column 27, lines 49-67). As such, one would have recognized the inoculum of Barach as being suitable for culturing in the presence of added purine according to Dickely and it follows that one would have used the inoculum taught by Barach for culturing the strain of Dickely in the absence of purine in order to achieve a proper comparison and there is no objective evidence to the contrary.

Beginning at p. 14, applicant addresses claims 36 and 41, arguing that acidification can only be achieved by use of a particular inoculum. Although applicant does not dispute that the inoculum taught by Barach for culturing the strain of Dickely would not achieve the recited pH, applicant argues that one would not have used the inoculum of Barach, again relying on alleged "general scientific principles" asserted to be supported by the reference of Dickely.

Applicant's argument is not found persuasive. As noted above, while applicant asserts that in view of "general scientific principles", one would not have used the inoculum of Barach, there is no objective evidence of record to support this allegation and thus appears to be speculation. The examiner acknowledges applicant's reliance on teachings of Dickely that allegedly support this position, however, no such teachings appear to be present in the reference of Dickely as relied upon in the rejection.

At least for the reasons of record and the reasons set forth above, the examiner maintains that the methods of claims 11, 34, 36, 39, and 41-42 would have been *prima facie* obvious at the time of the invention.

The rejection of claim 28 under 35 U.S.C. 103(a) as being unpatentable over Dickely as evidenced by as evidenced by Luksas as applied to claims 1, 9-10, 17, 24, 30-31, 37, and 43 above and further in view of Nilsson is maintained for the reasons of record and the reasons set forth below. The rejection was fully explained in a prior Office action. See [16] beginning at p. 15 of the Office action mailed on 3/30/10.

Beginning at p. 15 of the instant remarks, applicant addresses claim 28 arguing that Nelson fails to remedy the alleged deficiencies of Dickely and Luksas.

Applicant's argument is not found persuasive. At least for the reasons of record and the reasons set forth above, the examiner maintains that the method of claim 28 would have been *prima facie* obvious at the time of the invention.

The rejection of claim 32 under 35 U.S.C. 103(a) as being unpatentable over Dickely as evidenced by as evidenced by Luksas as applied to claims 1, 9-10, 17, 24, 30-31, 37, and 43 above and further in view of Jochimsen is maintained for the reasons of record and the reasons set forth below. The rejection was fully explained in a prior Office action. See [17] at p. 17 of the Office action mailed on 3/30/10.

At p. 16 of the instant remarks, applicant addresses claim 32 arguing that Jochimsen fails to remedy the alleged deficiencies of Dickely and Luksas.

At least for the reasons of record and the reasons set forth above, the examiner maintains that the method of claim 32 would have been *prima facie* obvious at the time of the invention.

Claims 29, 35, and 40 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Steadman whose telephone number is 571-272-0942. The examiner can normally be reached on Mon to Fri, 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/David J. Steadman/
Primary Examiner, Art Unit 1656